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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/686,053	10/14/2003	Michael E. Jolley	02-1106-A	7002

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/686,053	JOLLEY ET AL.	
	Examiner	Art Unit	
	Vanessa L. Ford	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 March 2007*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8 and 14-20* is/are pending in the application.

4a) Of the above claim(s) *14-18 and 20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8 and 19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Action is responsive to Applicant's Amendment and Response filed March 1, 2007. Claims 9-13 have been canceled. Claims 14-18 and 20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. Claims 1-8 and 19 are under examination.

Objection/Rejections Withdrawn

2. In view of Applicant's amendment and response the following objection/rejections are withdrawn:

(a) objection to the specification, page 2, paragraph 2 of the previous Office action.

(b) Double patenting rejection, pages 4-5, paragraph3 of the previous Office action.

(c) Rejection of claims 1-8 and 19 under 35 U.S.C. 112 second paragraph, page 5, paragraph 4.

(d) Rejection of claims 1, 3-8 and 19 under 35 U.S.C. 102(a), pages 6-7, paragraph 5.

(e) Rejection of claims 1-4, 6-8 and 19 under 35 U.S.C.102(b), pages 7-8, paragraph 6.

(f) Rejection of claims 1-8 and 19 under 35 U.S.C. 103(a), pages 8-10, paragraph 7.

New Grounds of Rejection

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-4, 6-8 and 19 are rejected under 35 U.S.C. 103(a) as unpatentable over Bolz *(U.S. Patent No.4,067,959 published January 10,1978)* in view of Nasir et al *(Proceedings One Hundred and Fourth Annual Meeting of the United States Animal Health Association, October 20-27, 2000, Birmingham, AL).*

Claims 1-4, 6-8 and 19 are drawn to a method for detecting *Salmonella* antigens in a sample, said method comprising the steps of combining said sample with a tracer an anti-*Salmonella* antibody to form an assay mixture said tracer comprising a fluorophore conjugated to an oligosaccharide from a *Salmonella* cell wall lipopolysaccharide said tracer being able to bind to said anti-*Salmonella* antibody to produce a detectable change in fluorescence polarization and measuring the fluorescence polarization of said assay mixture to obtain a measured fluorescence polarization value wherein said measured fluorescence polarization value is related to the concentration of *Salmonella* antigens in said sample.

Bolz teaches a method of detecting antigens in a sample comprising contacting the antibodies specific to the antigen with the sample containing the antigen (see the Abstract and columns 5-6). Bolz et al teach that this method is performed in assay format (see the Abstract). Bolz teaches that the method of the invention includes using fluorogen labels for detection (see the Abstract). Bolz teaches that the antigen or antibody can be placed on as solid support surface depending upon which is the target molecule in the sample (See the Abstract).

Bolz do not teach using a tracer comprising a fluorophore conjugated to an oligosaccharide from *Salmonella* cell wall lipopolysaccharides or the use of fluorescence polarization.

Nasir et al teach a detecting using fluorescence polarization to detect *Salmonella enteritidis* infections in chickens by using the O -polysaccharide of S. enteritidis and an ELISA with an S. enteritidis flagellin antigen (see the Abstract). Nasir et al teach that the fluorescein used in the method is isothiocynate isomer (Materials and Methods, Section 2). Nasir et al teach that serum samples (cultured samples) as well as egg yolk (food product) were tested for *Salmonella* (Section 2.5). Nasir et al teach that a blank serum reading was taken which included a diluted tracer added and mixed and the fluorescence polarization value taken (see the Abstract). Nasir et al teach that a positive sample was indicated by a reading of 10mP higher than that of the tracer buffer (see the Abstract). Therefore, Nasir et al teach the claim limitations "the method of claim 1, wherein combining said sample with a tracer and an anti-*Salmonella* antibody to form an assay mixture comprises combining said sample with anti-*Salmonella*

antibody to provide a bank mixture and combining said blank with said tracer to provide said assay mixture", "measuring the fluorescence polarization of said blank mixture to provide a blank fluorescence polarization value" and subtracting said blank polarization value from said measured fluorescence polarization value to provide a blank-corrected fluorescence polarization value, wherein said measured fluorescence polarization value is related to the concentration of *Salmonella* antigens in said sample" because these claim limitations are necessarily taught by using fluorescence polarization.

It would have been *prima facie* obvious at the time the invention was made to modify the method of detecting as taught by Bolz to include a tracer prepared from the O-polysaccharide of *S. enteritidis* and an immunoassay (ELISA) format with an *S. enteritidis* flagellin antigen according to the teachings of Nasir et al because Nasir et al teach that fluorescence polarization is highly specific, sensitive and an accurate method in which to detect *Salmonella* in biological samples. It would be expected absent evidence to the contrary that a method of detecting antigen can be performed by combining antibodies specific for the target antigen (e.g. *Salmonella)* and a tracer because Nasir et al has demonstrated the immune complex formed by the contact of the antibodies and the antigen are detectable by fluorescence polarization, thereby accurately detecting poultry samples that are infected with *Salmonella.*

4. Claim 5 is rejected under 35 U.S.C. 103(a) as unpatentable over Bolz and Nasir et al as applied to claims 1-4, 6-8 and 19 above and further in view of Gast et al*(Avian Diseases, 46:137-142, Jan-March, 2002).*

Claim 5 is drawn to the method of claim 1 wherein said sample is from animal feces.

The teachings of Bolz and Nasir et al have been described previously.

Bolz and Nasir et al do not teach the claim limitation wherein said sample is from animal feces.

Gast et al teach that fluorescence polarization is an effective and accurate method to detect *Salmonella* in animal (hen) feces. Gast et al teach that detecting *Salmonella* in feces samples is a fast and effective method to determine *Salmonella* infection in poultry.

It would have been *prima facie* obvious at the time the invention was made to modify the method of detecting as taught by Bolz and Nasir et al as combined above because Gast et al teach fluorescence polarization to fast and effective method to detect *Salmonella* in animal (hen) feces thereby accurately identifying *Salmonella* infections in poultry. It would be expected absent evidence to the contrary that a method of detecting antigen in feces can be performed by combining antibodies specific for the target antigen and a tracer from the O-polysaccharide of *S. enteritidis* because Nasir et al and Gast et al has demonstrated that fluorescence polarization is a fast, sensitive and accurate method in which to detect *Salmonella* in biological samples. Additionally, Bolz teaches that antibodies specific to a target antigen can be used to detect said antigen in biological samples.

Status of Claims

5. No claims allowed.

Conclusion

6. Any inquiry of the general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308–0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Office Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for the Group 1600 is (703) 872-9306.

Any inquiry concerning this communication from the examiner should be directed to Vanessa L. Ford, whose telephone number is (571) 272-0857. The examiner can normally be reached on Monday – Friday from 9:00 AM to 6:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew, can be reached at (571) 272-0787.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov./>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vanessa L. Ford
Biotechnology Patent Examiner
May 5, 2007

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER